REMARKS

Claims 1-3, 5-19, 21-32 and 75-84 were examined. Claims 1-2 and 17-18 are canceled. Claims 3, 5, 8, 19, 21 and 24 are amended. Claims 3, 5-16, 19, 21-32 and 75-84 remain in the Application.

The Patent Office objects to claims 5-7, 21-23 and 79-81 as dependent upon a rejected base claim, but otherwise finds such claims allowable over the prior art of record. The Patent Office finds claims 75-77 allowable over the prior art of record. The Patent Office rejects claims 1-3, 8 and 17-19 under 35 U.S.C. §102(e). Finally, the Patent Office rejects claims 1-3, 8-11, 17-19, 24-27, 78 and 82-84 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. Objection to Claims 5-7, 21-23 & 79-81

The Patent Office objects to claims 5-7, 21-23 and 79-81 as dependent upon a rejected base claim, but otherwise finds such claims allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Applicant amends claims 5 and 21 to incorporate the limitations of the base claim and an intervening claim (claims 1 and 2 for claim 5, and claims 17 and 18 for claim 21). Accordingly, Applicant respectfully requests that the Patent Office withdraw the objection to claims 5-7 and 21-23.

With respect to claims 79-81, Applicant does not amend any claim to incorporate the limitations of a base claim and any intervening claims. As discussed below with respect to claim 78, Applicant believes claims 79-81 as written are allowable. Accordingly, Applicant respectfully requests that the Patent Office withdraw the objection to claims 79-81.

B. 35 U.S.C. §102(e): Rejection of claims 1-3, 8 & 17-19

The Patent Office rejects claims 1-3, 8 and 17-19 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,835,193 of Epstein, et al. (Epstein). Epstein describes a flexible tissue injection catheter to accomplish injections at a controlled depth. See Abstract. The preferred embodiment shown in Figures 5 and 6 of Epstein, the injection catheter includes needle stop 500 enclosing a proximal portion and a distal portion of injection needle 515. Needle stop 500 includes outer needle holder 510 and a needle carriage 520 having an interior shaped to receive

the proximal and distal portion of needle 515. Needle carriage 520 is slideably mounted within needle holder 510 for movement between a fully recessed position and a series of advanced positions in which the distal tip of a needle is progressively advanced to expose the controlled increments of the distal tip thereof. Locking mechanism 525, shown as a tightening screw, locks the position of the needle carriage with respect to the needle holder during use of the needle for injections. See column 12, lines 12-51. Epstein does not describe that locking mechanism 525 maintains an orientation of injection needle 515. For example, although locking mechanism 525 may inhibit the advancement of needle carriage 520, it does not follow that a needle within needle carriage 520 may not rotate from one radial orientation to a second radial orientation.

Claims 1-2 of the Application are canceled rendering their rejection under 35 U.S.C. §102(e) moot. Claim 8 incorporates the limitations of claims 1 and 2 and further describes a catheter body and a hub coupled to a proximal end of the catheter body. A needle extends through the hub and is maintained in a prescribed radial orientation.

Claim 8 is not anticipated by Epstein, because Epstein does not describe an apparatus comprising a needle, a catheter body having a dimension at a proximal end to contain the needle and a hub coupled to the proximal end of the catheter body, wherein the needle extends through the hub and is maintained in a prescribed radial orientation. The Patent Office points to locking mechanism 525 of Epstein for maintaining a prescribed orientation. As noted above, however, Epstein is silent with respect to the function of locking mechanism 525 in the radial orientation of injection needle 515.

Claim 3 is amended to depend from claim 8. For the reason stated above with respect to claim 8, Applicant believes claim 3 is not anticipated by Epstein.

Claims 17-18 are canceled, thus rendering the rejection under 35 U.S.C. §102(e) moot. Claim 19 depends from claim 21 which, as noted above, now incorporates the limitations of claims 17-18 and is allowable over the prior art of record.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 3, 8 and 19 under 35 U.S.C. §102(e).

C. 35 U.S.C. §103(a): Rejection of Claims 1-3, 8-11, 17-19, 24-27, 78 & 82-84

The Patent Office rejects claims 1-3, 8-11, 17-19, 24-27, 78 and 82-84 under 35 U.S.C. §103(a) as obvious over Epstein in view of U.S. Patent No. 6,217,554 of Green (Green). Epstein is cited for describing an injection device including an expandable body, at least one delivery cannula, and a needle disposed a lumen with a protuberance defining a sleeve thereon close to a distal delivery end, a first stop and a second stop defining a diameter less than the outer diameter of the protuberance of the needle and located distal and proximal to the protuberance. Green is cited for teaching an injection catheter comprising a cannula member, expandable balloon, movable needle assembly, and a needle hub, wherein the hub is capable of maintaining the needle in a specific axial depth and radial orientation.

Catheter 10 of Green includes outer sheath 11, tubular member 25 and inner member 30. Tubular member 25 may include ring 34, formed of a layer of radio-opaque marker material that may be used to assist in orienting catheter 10 so that the distal end of tubular member 25 is aligned with a desired treatment site in the patient's vasculature. See column 4, lines 4-12. Annular lumen 31 extends from proximal end of catheter 10. Hollow needles 28 protrude longitudinally from distal endface 29 and are in fluid communication with annular lumen 31. Hollow needles 28 are disposed in a semi-circular pattern which ensures that when the catheter is inserted and properly oriented, for example, in the coronary sinus or great cardiac vein, the needles will extend only into the myocardium, and not puncture the circumference of the needle adjacent the pericardial sac. See column 4, lines 23-38. Based on this discussion, Green uses the semi-circular pattern arrangement of needles 28 and ring 34 to orient the needles for delivery into, for example, the myocardium. Green is silent as to orienting the needles so that they maintain a prescribed radial orientation.

As noted above, claims 1-2 are canceled, thus rendering the rejection under 35 U.S.C. §103(a) moot. Claim 8 is not obvious over the cited references because the references do not teach an apparatus including a needle, a catheter body comprising a dimension to contain the needle, and a hub coupled to a proximal end of the catheter body, wherein the needle extends through the hub and is maintained in a prescribed radial orientation. As noted above, neither Epstein nor Green teaches maintaining a prescribed radial orientation and there is no motivation from either reference for maintaining a radial orientation.

Claims 3 and 9-11 depend from claim 8 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 8, claims 3 and 9-11 are not obvious over the cited references.

Claims 17 and 18 are canceled, thus rendering the rejection under 35 U.S.C. §103(a) moot.

Claim 19 depends from claim 21 which was not rejected under 35 U.S.C. §103(a). Accordingly, claim 19 is not obvious over the cited references.

Claim 24 describes an apparatus including, among other things, a needle, a catheter body having a dimension at a proximal end to contain the needle, a hub coupled to a proximal end of the catheter body, wherein the needle extends though the hub and is maintained in a prescribed radial orientation. As noted above with respect to claim 8, claim 24 is not obvious over the cited references, because the references fail to describe or provide any motivation for maintaining a needle in a prescribed radial orientation. The references describe maintaining an injection distance (Epstein) and a relative position upon injection (Green), but neither reference mentions or describes a radial orientation once a needle is injected.

Claims 25-27 depend from claim 24 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 24, claims 25-27 are not obvious over the cited references.

Claim 78 describes an apparatus including a balloon catheter comprising a cannula, at least one needle, and a hub coupled to a proximal portion of the cannula and retaining the at least one needle according to a prescribed radial orientation by a protuberance on a proximal portion of the needle. Claim 78 is not obvious over the cited reference because the references fail to describe an apparatus including a hub coupled to a proximal portion of a cannula and retaining a needle according to a prescribed radial orientation by second protuberance on a proximal portion of the needle. As noted above with respect to claims 8 and 21, the references are silent and provide no motivation for maintaining a radial orientation with respect to their needles.

Claims 82-84 depend from claim 78 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 78, claims 82-84 are not obvious over the cited references.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 3, 8-11, 19, 24-27, 78 & 82-84 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

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William Thomas Babbitt, Reg. No. 39,591

12400 Wilshire Boulevard
Seventh Floor
Los Angeles, California 90025
Telephone (310) 207-3800
Facsimile (310) 820-5988

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Suzanne Johnston — 1/16/07 Date